

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.** CE 597192  
**Issued To:** **Blue Medical Devices B.V.**  
**Panovenweg 7**  
**5708 HR Helmond**  
**The Netherlands**

In respect of:

**Summit, XTRM-Summit, Everest, Force, Force NC, XTRM-Force, XTRM-Way 3, Welling Medical Summit, Welling Medical Everest and Welling Medical Force PTCA Catheters.**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **27 July 2016**

Date: **07 March 2017**

Expiry Date: **14 March 2022**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

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## Supplementary Information to CE 597192

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### Summit, XTRM-Summit:

| Diameter (in mm) |    |                  |                  |                  |
|------------------|----|------------------|------------------|------------------|
| Length (in mm)   |    | 1.10             | 1.25             | 1.50             |
|                  | 10 | SUM1110/XSUM1110 | SUM1210/XSUM1210 | SUM1510/XSUM1510 |
|                  | 15 | SUM1115/XSUM1115 | SUM1215/XSUM1215 | SUM1515/XSUM1515 |
|                  | 20 | SUM1120/XSUM1120 | SUM1220/XSUM1220 | SUM1520/XSUM1520 |

### Everest:

| Diameter (in mm) |    |          |          |          |          |          |          |          |          |          |
|------------------|----|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| Length (in mm)   |    | 1.50     | 2.00     | 2.25     | 2.50     | 2.75     | 3.00     | 3.25     | 3.50     | 4.00     |
|                  | 10 | EVER1510 | EVER2010 | EVER2210 | EVER2510 | EVER2710 | EVER3010 | EVER3210 | EVER3510 | EVER4010 |
|                  | 15 | EVER1515 | EVER2015 | EVER2215 | EVER2515 | EVER2715 | EVER3015 | EVER3215 | EVER3515 | EVER4015 |
|                  | 20 | EVER1520 | EVER2020 | EVER2220 | EVER2520 | EVER2720 | EVER3020 | EVER3220 | EVER3520 | EVER4020 |
|                  | 30 | EVER1530 | EVER2030 | EVER2230 | EVER2530 | EVER2730 | EVER3030 | EVER3230 | EVER3530 | EVER4030 |

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### Force, Force NC, XTRM-Force:

|                |    | Diameter (in mm) |          |          |          |          |          |          |          |          |          |
|----------------|----|------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
|                |    | 2.00             | 2.25     | 2.50     | 2.75     | 3.00     | 3.25     | 3.50     | 3.75     | 4.00     | 4.50     |
| Length (in mm) | 5  | XFOR2005         | XFOR2205 | XFOR2505 | XFOR2705 | XFOR3005 | XFOR3205 | XFOR3505 | XFOR3705 | XFOR4005 | XFOR4505 |
|                | 10 | XFOR2010         | XFOR2210 | XFOR2510 | XFOR2710 | XFOR3010 | XFOR3210 | XFOR3510 | XFOR3710 | XFOR4010 | XFOR4510 |
|                | 15 | XFOR2015         | XFOR2215 | XFOR2515 | XFOR2715 | XFOR3015 | XFOR3215 | XFOR3515 | XFOR3715 | XFOR4015 | XFOR4515 |
|                | 20 | XFOR2020         | XFOR2220 | XFOR2520 | XFOR2720 | XFOR3020 | XFOR3220 | XFOR3520 | XFOR3720 | XFOR4020 | XFOR4520 |

### XTRM-Way 3:

|                |    | Diameter (in mm) |        |        |        |        |        |        |        |        |
|----------------|----|------------------|--------|--------|--------|--------|--------|--------|--------|--------|
|                |    | 1.50             | 2.00   | 2.25   | 2.50   | 2.75   | 3.00   | 3.25   | 3.50   | 4.00   |
| Length (in mm) | 10 | XW1510           | XW2010 | XW2210 | XW2510 | XW2710 | XW3010 | XW3210 | XW3510 | XW4010 |
|                | 15 | XW1515           | XW2015 | XW2215 | XW2515 | XW2715 | XW3015 | XW3215 | XW3515 | XW4015 |
|                | 20 | XW1520           | XW2020 | XW2220 | XW2520 | XW2720 | XW3020 | XW3220 | XW3520 | XW4020 |
|                | 25 | XW1525           | XW2025 | XW2225 | XW2525 | XW2725 | XW3025 | XW3225 | XW3525 | XW4025 |
|                | 30 | XW1530           | XW2030 | XW2230 | XW2530 | XW2730 | XW3030 | XW3230 | XW3530 | XW4030 |

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### Welling Medical Summit:

|                   |    | Diameter (in mm) |          |          |
|-------------------|----|------------------|----------|----------|
| Length<br>(in mm) |    | 1.10             | 1.25     | 1.50     |
|                   | 10 | WSUM1110         | WSUM1210 | WSUM1510 |
|                   | 15 | WSUM1115         | WSUM1215 | WSUM1515 |
|                   | 20 | WSUM1120         | WSUM1220 | WSUM1520 |

### Welling Medical Force:

|                   |    | Diameter (in mm) |          |          |          |          |          |          |          |          |          |
|-------------------|----|------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| Length<br>(in mm) |    | 2.00             | 2.25     | 2.50     | 2.75     | 3.00     | 3.25     | 3.50     | 3.75     | 4.00     | 4.50     |
|                   | 5  | WFOR2005         | WFOR2205 | WFOR2505 | WFOR2705 | WFOR3005 | WFOR3205 | WFOR3505 | WFOR3705 | WFOR4005 | WFOR4505 |
|                   | 10 | WFOR2010         | WFOR2205 | WFOR2510 | WFOR2710 | WFOR3010 | WFOR3210 | WFOR3510 | WFOR3710 | WFOR4010 | WFOR4510 |
|                   | 15 | WFOR2015         | WFOR2205 | WFOR2515 | WFOR2715 | WFOR3015 | WFOR3215 | WFOR3515 | WFOR3715 | WFOR4015 | WFOR4515 |
|                   | 20 | WFOR2020         | WFOR2205 | WFOR2520 | WFOR2720 | WFOR3020 | WFOR3220 | WFOR3520 | WFOR3720 | WFOR4020 | WFOR4520 |

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### Welling Medical Everest:

|                |    | Diameter (in mm) |          |          |          |          |          |          |          |          |
|----------------|----|------------------|----------|----------|----------|----------|----------|----------|----------|----------|
|                |    | 1.50             | 2.00     | 2.25     | 2.50     | 2.75     | 3.00     | 3.25     | 3.50     | 4.00     |
| Length (in mm) | 10 | WEVE1510         | WEVE2010 | WEVE2210 | WEVE2510 | WEVE2710 | WEVE3010 | WEVE3210 | WEVE3510 | WEVE4010 |
|                | 15 | WEVE1515         | WEVE2015 | WEVE2215 | WEVE2515 | WEVE2715 | WEVE3015 | WEVE3215 | WEVE3515 | WEVE4015 |
|                | 20 | WEVE1520         | WEVE2020 | WEVE2220 | WEVE2520 | WEVE2720 | WEVE3020 | WEVE3220 | WEVE3520 | WEVE4020 |
|                | 30 | WEVE1530         | WEVE2030 | WEVE2230 | WEVE2530 | WEVE2730 | WEVE3030 | WEVE3230 | WEVE3530 | WEVE4030 |

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## Certificate History

| Date              | Reference Number | Action  |
|-------------------|------------------|---|
| 27 July 2016      | 10160304         | First Issue – Transfer from another Notified Body |
| 16 September 2016 | 10166418         | Corrected address error.                          |
| 07 March 2017     | 10168855         | Certificate renewal                               |

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